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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,820	02/19/2002	Todd K. Whitehurst	AB-116U	3079

23845 7590 10/06/2006

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EXAMINER	
BOCKELMAN, MARK	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/081,820	WHITEHURST ET AL.
	Examiner	Art Unit
	Mark W. Bockelman	3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 17 July 2006.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-5,8,14-16,36-38 and 41 is/are pending in the application.

4a) Of the above claim(s) 37 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5,8,14-16,36,38 and 41 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 7-18-2006.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claim 37 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2-9-2005. Claim 37, which specifies stimulation of the vagus nerve portion affecting the pancreas, would not appear to treat headaches, i.e. the elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 8, 14-16, 36, 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman 6,164,284, Loeb USPN 5,312,439 or 5,324,316, each in further view of Adkins et al USPN 5,928,272, Terry, Jr et al. USPN 5,540,730 Schwartz et al. USPN 5,330,507, Terry, Jr et al USPN 5,335,657, or Rutecki et al USPN 5,330,515.

Loeb '439 and '316 teach a nerve stimulating device for implantation which receives pulsing information from an external source, has power provided to it, is leadless and generates pulses to stimulate nerve cells. Each is recognized as being useful by applicant to serve the purpose of stimulating at the recited location in the claim

(see applicant's specifcation pages 9 and 10). Applicant differs in his choice of location and purpose to be served. Each of the secondary references teach the stimulation of various portions of the vagus nerve for accomplishing those tasks recited by applicant, i.e. headache, epilepsy, gastro-intestinal disorders etc. To have taken an old an well known device and substituted it for a device that performs the same function in an old and well known method for achieving the same result would have been obvious to anyone of ordinary skill in the art. Each of the secondary references additionally provides for sensing patient conditions and to have included those sensors on the Loeb devices for performing the same functions would have been obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 8, 14-16, 36, 38, and 41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-19 of U.S. Patent No. 6,735,475 in view of USPN 5,330,515. Applicant claims substantially the same method claimed in claim 13 of the '475 patent for headache treatment, but

does specify the vagus nerve as the location for treatment. Rutecki et al ' 515 is provided as evidence that given the claim of the '475 patent, the use of the device for stimulation a vagus nerve for treating pain would have been obvious.

Terminal Disclaimer

The application/patent being disclaimed has been improperly identified since the number used to identify the patent being disclaimed is incorrect. The correct number is 6,735,475.

An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c).

Response to Arguments

Applicant's arguments filed 3-27-2006 and 7-17-2006 have been fully considered but they are not persuasive. Applicant argues that the combination of references applied in the rejection of the claims requiring a leadless stimulator would not be appropriate because the secondary references use leads for sensors. First, many of the claims do not require any type of sensor, only s couple of dependent claims. The Loeb and Schulman references are microstimulators and can be used for stimulating a variety of body tissues. Secondly, because many of the claims do not discuss the senor portion of the device and thus do not specify that the sensor is leadless as well, the examiner takes the position the microstimulator portion in the references are leadless and the

connection of a lead sensor to a sensor portion is not excluded. Thirdly, the secondary references do not require the use of sensors such as the Terry '086 reference which may or may not use implanted electrodes in the brain. The device may be activated by the patient external manual activation (column 6 lines 43-51) and to thus to the claims that do not require a sensor, all of the rejections are deemed appropriate. Finally, the examiner has added Schulman as a primary reference which discloses the use of an implantable device that includes a sensor portion either inside of the stimulator housing or as a separate implantable unit communicating with the microstimulator. To have used either of these techniques in schemes such as the Terry schemes for treating migraines would have been obvious. The examiner believes that there is ample motivation for combining the references since the devices used are all old and well known implanted stimulators (as noted in applicant's specification page 10) and the recited treatments that were all old and well known that use the implanted stimulator. It would have been obvious to substitute the stimulators of Loeb and Schulman in the Terry (eg) references due to their smaller size and ease of implantation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 10:00 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272 -6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Bockelman

MARK BOCKELMAN
PRIMARY EXAMINER

MWB

September 29, 2006